

**REMARKS**

In the present amendment, claim 1 has been amended and claims 11-13 have been canceled. Accordingly, claims 1-8, 10, 14, 16, and 19-21 are pending in the present application with claim 1 being independent. Support for the amendment can be found, e.g., at page 7, lines 18-21, and page 8, lines 7-8 and 16-18. No new matter has been added.

Response to Claim Rejections Under 35 U.S.C. § 103(a)

The Office Action makes the following claim rejections under 35 U.S.C. § 103(a):

- claims 1-8, 10, 14, 16, and 19-21 as allegedly being unpatentable over Carrison et al. (U.S. Published Application No. 2005/0038517, hereinafter “Carrison”) in view of Kim et al. (U.S. Patent No. 5,645,596, hereinafter “Kim”) and further in view of Tofighi et al. (U.S. Published Application No. 2003/0120351, hereinafter “Tofighi”);

- claims 11-13 as allegedly being unpatentable over Carrison in view of Kim and further in view of Tofighi as applied to claim 1, and further in view of Shimp (U.S. Published Application No. 2004/0052829).

The Action asserts that with regard to claim 1, Carrison discloses the invention substantially as claimed, but fails to disclose that the bone replacement material is calcium phosphate and has a porosity equal to or less than 75%. The Action relies on Kim to remedy this deficiency. The Action admits, however, that Carrison and Kim fail to specifically state that the collapsing strength of the calcium phosphate based compound has a collapsing strength of 15MPa or more. The Action relies on Tofighi to remedy this deficiency.

The Action contends that Figure 3 of Carrison teaches claims 2-4, 10 and 14; Figures 13-18 of Carrison to teach claims 16, 20, and 21; and the shapes recited in claims 5-8 are obvious over Carrison because, allegedly, shapes are simply a design choice, which would be obvious.

The Action admits that Carrison, Kim and Tofighi fail to disclose that the specific size of the pellets is between 2 and 10 mm or the volume of each pellet is in the range of 13 to 239 mm<sup>3</sup>. The Action relies on Shimp to remedy this deficiency, stating that Shimp teaches calcium phosphate pellets where the pellets can vary in size but are preferably up to 4 mm. The Action goes on to infer that the volume of the pellets disclosed in Shimp would be 64 mm<sup>3</sup>. Applicants respectfully disagree with the Action's assertions.

Applicants initially note that claim 1 has been amended to incorporate the elements of claims 11-13, and claims 11-13 have been canceled.

With respect to the 35 U.S.C. § 103(a) rejections, Applicant submit that Carrison, Kim, Tofighi, and Shimp do not teach or suggest the subject matter of claims 1-8, 10, 14, 16, and 19-21. In particular, Applicants submit that neither Carrison, Kim, Tofighi, nor Shimp, alone or in combination, teach or suggest, at least, "[a] bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material consists essentially of a calcium phosphate based compound and is formed into a pellet and satisfies both of the following conditions (I) and (II): (I) porosity is equal to or less than 75%; and (II) collapsing strength is equal to or more than 15Mpa, and wherein the pellet has a roughly polyhedral shape and, wherein the pellet is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces, one of the opposite, non-parallel surfaces being inclined at a predetermined angle with respect to the other of the opposite, non-parallel surfaces, and wherein the bone replacement material is in a state such that a number of pellets of the bone replacement material are introduced into a cavity of the bone defective part and are aggregated therein, and wherein each pellet of the roughly polyhedral shape is defined by a plurality of edges having different lengths, in which the length of the longest edge is in the range of 5 to 10 mm and the length of

the shortest edge is in the range of 2 to 5 mm, wherein the volume of each pellet of the bone replacement material is in the range of 13 to 239 mm<sup>3</sup>.”

Applicants submit that Shimp fails to remedy the deficiencies of Carrison, Kim, and Tofighi. The Action alleges that Shimp teaches pellets that “can vary in size but are preferably up to 4 mm”; however, Shimp does not teach all the elements of, at least, claim 1. For example, Shimp does not teach that *the length of the longest edge is in the range of 5 to 10 mm, the length of the shortest edge is in the range of 2 to 5 mm, or the volume of each pellet of the bone replacement material is in the range of 13 to 239 mm<sup>3</sup>*. Shimp teaches that varying sizes of support elements (pellets) are *up to 4 mm*, thus, specifically excluding pellets having lengths in the range of 5 to 10 mm, as recited in claim 1 (see Shimp, paragraph [0029]).

Moreover, Shimp fails to disclose any volume for the pellets, and even with the Action’s inferred volume of the pellets, Shimp does not teach all the elements of the claimed invention. As a result, Shimp cannot exhibit the effects of the present invention, such as making the packing of the bone replacement material into a bone defective part more smooth, reliable, and safe (specification, page 7, lines 20-25).

Furthermore, Applicants submit that there is no reason or motivation to modify the teachings of Carrison, Kim, and Tofighi in view of Shimp to arrive at the present invention. In fact, Shimp teaches away from the present invention as recited in claim 1. As stated above, Shimp teaches support elements (pellets) up to 4 mm in size; excluding pellets having the lengths in the range of 5 to 10 mm, as recited in claim 1 (see Shimp, paragraph [0029]). Furthermore, Shimp teaches that the support elements (pellets) are preferably spherical or approximately spherical, which contrasts drastically to the polyhedral pellet shape recited in claim 1 (see Shimp, paragraph [0029]). Applicants submit that Shimp teaches one of ordinary skill in the art that the

spherical or approximately spherical support elements (pellets) should be up to 4 mm. Consequently, Shimp teaches a person of ordinary skill in the art away from the claimed invention. Applicants therefore submit that there is no reason or motivation to modify Carrison, Kim, Tofighi, or Shimp to arrive at the present invention.

Applicants further submit that even if, assuming *arguendo*, Carrison, Kim, and Tofighi, and Shimp were combinable, they would not teach or suggest all the elements of claims 1-8, 10, 14, 16, and 19-21.

In view of the foregoing, Applicants respectfully request that the rejection to claims 1-8, 10, 14, 16, and 19-21 be withdrawn.

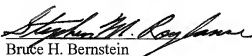
### CONCLUSION

In view of the foregoing, the rejections of record should be withdrawn, and the application allowed.

Accordingly, reconsideration of the outstanding Office Action and allowance of the present application and all the claims therein are respectfully requested and now believed to be appropriate.

Should there be any questions or if any issues remain which can be resolved by phone, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,  
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